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Via EMAIL and ECF

The Honorable Robert W. Lehrburger
United States Magistrate Judge
Daniel Patrick Moynihan, United States Courthouse
U.S. District Court for the Southern District of New York
500 Pearl Street, Room 1960
New York, NY 02903

Re: *Sergeants Benevolent Ass'n Health & Welfare Fund, et. al. v. Actavis, PLC, et al*, No. 15-cv-06549-CM (S.D.N.Y.)

Dear Judge Lehrburger:

I write on behalf of Sergeants Benevolent Association Health & Welfare Fund ("SBA" or "EPP") in opposition to Defendants' request for discovery relating to any "Alzheimer's treatments" in addition to Namenda IR, Namenda XR, (memantine) and their AB-rated[1] generic equivalents. To allow such discovery would be contrary to antitrust jurisprudence, would conflict with Judge McMahon's separate rulings on market power (sometimes called monopoly power) and class certification.

Please note that the FDA has approved only four drugs to treat Alzheimer's disease: Aricept, Exelon, Razadyne, and Namenda. These four are currently on the market. https://www.alz.org/alzheimers-dementia/treatments/medications-for-memory The FDA previously approved Cognex but it was later withdrawn from the market in 2012. All these drugs except Namenda are acetylcholinesterase inhibitors ("CIs") and work in the same basic manner. *Id.* The only other Alzheimer's drugs, acetylcholinesterase inhibitors ("AChEIs" or "CIs"), work differently from *and are not substitutable* for Namenda, an N–Methyl D–Aspartate ("NMDA") receptor antagonist and that works differently from CIs. *See New York ex rel. Schneiderman v. Actavis PLC,* 2014 WL 7015198, *5 (emphasis added.)

[1] AB-rated drugs are those that have demonstrated the bioequivalence standards established by the FDA. At the pharmacy, generic substitution is the process by which an AB-rated generic equivalent is dispensed rather than the brand-name drug, whereas, non-AB rated products may not be substituted by the pharmacist without the permission from the doctor.

Despite this established record in the underlying action brought by the New York Attorney General and held applicable to the Direct Purchaser Action, and now arguably this action, Defendants, under the guise of class certification discovery, seek discovery on what they refer to as evidence of "switching" between Namenda products and "other Alzheimer's Treatments" such as CIs. Defendants are using the discovery device to seek a redo of their previously failed argument and take this Court back to square one of the product market analysis by allowing discovery on other, irrelevant drugs, in an attempt to expand the defined product market to include CIs. Defendants are simply recycling previous arguments that have already been rejected. *See New York ex rel. Schneiderman v. Actavis PLC,* 2014 WL 7015198, *14 (S.D.N.Y. Dec. 11, 2014)(Namenda I), affirmed, 787 F.3d 638 (2d Cir. 2015)("Namenda IR is not indicated for use with mild-stage Alzheimer's Disease patients" and "[D]octors do not consider CIs to be reasonable substitutes for Namenda.") Since Namenda and CIs do not have "reasonable interchangeability for the purposes for which they are produced," they are not part of the same product market. *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). As Judge Sweet found, trying to incorporate CIs and Namenda into broader categories of an "'Alzheimer's Drug Market' or . . . 'anti-dementia'" drugs is "akin to, perhaps, categorizing two distinct non-substitutable products such as a sponge and soap under the umbrella of cleaning supplies." *Namenda I.* Because the relevant market for the directs is the same relevant market for end payors in such pharmaceutical antitrust litigation, to allow defendants to go on this lark is the epitome of unnecessary and duplicative discovery.

Indeed, Judge McMahon ruled on December 26, 2018, subsequent to our appearance before Your Honor on this issue, that Actavis and Forest are collaterally estopped from relitigating the questions of "(1) whether [Forest] possessed monopoly power over the U.S. memantine market up until the entry of generic competition; (2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive; and (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct." *Sergeants Benevolent Association Health and Welfare Fund v. Actavis, PLC*¸ 1:15-cv-06549-CM, p. 29, (S.D.N.Y. Dec. 26, 2018).

Under basic antitrust jurisprudence, a relevant product market "is composed of products that have reasonable interchangeability for the purposes for which they are produced – price, use and qualities considered." *E. I. Du Pont de Nemours & Co.*, 351 U.S. at 404; *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.,* 386 F.3d 485, 496 (2d Cir. 2004)("[t]he goal in defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output."). Here, the relevant market is Namenda and its generic alternatives.

In generic exclusion antitrust cases such as this, single product markets are commonplace. *See, e.g.*, In re *Namenda Direct Purchaser Antitrust Litig.,* 2017 WL 4358244 (S.D.N.Y. May 23, 2017)(brand and generic Namenda only); *Geneva Pharms.,* 386 F.3d 485; *In re Nexium (Esomeprazole) Antitrust Litig.,* 968 F. Supp. 2d 367, 377-88 (D. Mass. 2013) (the jury could find a "single product" relevant market for Nexium because "[t]he fact that other drugs may be used to treat heartburn and related conditions is immaterial" and noting that "courts across the country

have on numerous occasions ruled that both a brand-name drug and its generic analogs can fall within the bounds of a relevant market"); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2013 U.S. Dist. LEXIS 111587, at *5-6 (D.N.J. Aug. 8, 2013); *In re Terazosin Hydrochloride Antitrust Litig.,* 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fl. 2005); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000)(plaintiffs adequately alleged a relevant market limited to Cardizem CD and its AB-rated bioequivalents); *United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund v. Teikoku Pharma USA (In re Lidoderm Antitrust Litig.)*, No. 14-md-2521, 2017 WL 5068533, *21 (N.D. Cal. Nov. 3, 2017) (granting partial summary judgment to plaintiffs on relevant market where defendants relied on qualitative evidence of interchangeability, such as formularies, instead of quantitative cross-elasticity of demand—price competition); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522–23 (E.D.N.Y. 2005) (on motion for summary judgment, court found relevant market consisting solely of ciprofloxacin, rejecting inclusion of drugs in the same molecular family). See also, *Geneva Pharms.,* 386 F.3d at 496-501 (relevant market was limited to generic warfarin sodium tablets.) *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, 07-cv-7343(HB), 2008 WL 169362, *7 (S.D.N.Y. Jan 18, 2008) (plaintiff alleged plausible relevant market limited to Arava (leflunomide) and its AB-rated equivalents).

Importantly, the relevant market in these pharmaceutical antitrust cases are the same for both the direct and indirect purchasers. Thus, defendants' attempt to redefine the product market for the end payors is inappropriate. The relevant product market is Namenda and the generic equivalents, as it is in both the NY AG case[2] and the related DPP case.[3]

In such cases where the product market was similarly defined, no such irrelevant discovery was allowed. *See, e.g, In re Aggrenox Antitrust Litig.*¸ 199 F.Supp.3d 662, 665 (D. Conn. 2016)("the only relevant market in this litigation is therefore the market of Aggrenox and its generic equivalents, and that no discovery or evidence relating to other drugs as potential substitutes is relevant.")

The proper inquiry at class certification is not every other drug besides Namenda, or even similar drugs to Namenda IR, Namenda XR, AB-rated generic equivalents. The relevant product market has implications for class certification analysis. Here the defendants argue, without support, that the end payors' relevant market alone should include the CIs, and thus the end payors should be treated differently from the direct purchasers as to how they measure impact and damages at class certification. That is wrong. The proper measure of impact at class certification is subject to economic analysis of aggregate damages calculated from data derived

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[2] *New York ex rel. Schneiderman v. Actavis, PLC* (*Namenda I*), No. 14 Civ 7473, 2014 WL 7015198 *35-36 (Dec. 11, 2014)(*aff'd sub nom*. *New York ex. rel. Schneiderman v. Actavis PLC* (*Namenda II*), 787 F.3d 638 (2d Cir. 2015)("The appropriate geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States.").

[3] Forest is precluded from relitigating the questions of whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition. *In re Namenda Direct Purchaser Antitrust Litig.* (*Namenda IV*), 2017 WL 4358244, *16 (S.D.N.Y. May 23, 2017).

from the entire Namenda market.

The impact on SBA and the end payor class members (among the End Payor Class members are: third party payors, such as SBA, other health and welfare funds, insurance companies, and fund participants, for example) will be measured by the analysis of the defendants' anticompetitive conduct which caused the delayed generic entry of Namenda IR.

Class certification under Fed. R. Civ. P. 23(a) is appropriate where (1) numerosity; (2) common issues of law and/or fact;(3) typicality, and (4) adequacy are found. Class certification under Fed. R. Civ. P. 23(b) is appropriate where (1) common issues predominate, and (2) a class action is superior and is manageable. Fed. R. Civ. P 23.

The discovery the defendants seek is not implicated by these elements. Defendants argue that somehow this discovery can address common issues of law of fact. That is not so. First, end payor plaintiff's theories of liability are necessarily premised on the defendants' conduct, not on issues particular to individual class members. In particular, market power has already been established directly. *See* Judge McMahon's Dec. 26, 2018 ruling. Common issues predominate as to antitrust impact as well where in order to prove antitrust impact, a plaintiff must show some damage due to a defendant's antitrust violations. *Zenith Radio Corp. v. Hazeltine Research,* 395 U.S. 100, 114, n.9 (1969). A plaintiff need only advance a plausible methodology to demonstrate that antitrust injury can be proven on a class-wide basis using common proof. *See In re DRAM Antitrust Litig.*, No. 02-md-1486, 2006 WL 1530166, at *9 (N.D. Cal. June 5, 2006). Here, EPPs allege antitrust injury in the form of overcharges that resulted from Defendants' agreements to delay generic competition. *See* Complaint. Expert testimony in this case will focus on the characteristics of the "but-for" world, *i.e.*, how the Namenda IR market would have behaved during the Class Period absent Defendants' unlawful conduct. Similarly, common issues as to measure of damages predominate.

Defendants made some cloaked reference this "Alzheimer's Treatment" discovery implicating an implied "ascertainability" requirement some courts have raised. To the extent that such a requirement exists here, SBA and the end payor class satisfy it without resorting to unnecessary discovery regarding other drugs specifically excluded from the relevant market. Any switch to a drug that is not a substitute is irrelevant.

A class is ascertainable if its members can be identified by reference to objective criteria and in an administratively feasible manner. *In re Nexium (Esomeprazole) Antitrust Litig.,* 777 F.3d 9, 19-20 (1st Cir. 2015); *Matamoros v. Starbucks Corp.,* 699 F.3d 129, 139 (a class was not "unascertainable and overbroad" where it was defined in terms of an "objective criterion"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2017 WL 4621777, at *13-14 (D. Mass. Oct. 16, 2017)(end-payor class ascertainable); 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1760, at 120–21 (2d ed.1986)) (criteria need only be "sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member."). Here, EPPs can identify class members by reference to the objective criteria in the class definition: (1) purchasers of Namenda IR, Namenda XR, and/or their generic equivalents, not for resale; (2) in applicable states; (3) during a discrete

time period. Class certification including impact and damages will be addressed at the appropriate stage in the litigation with an accompanying economic expert analysis.

For the foregoing reasons, the discovery defendants seek, both from SBA and third parties, do not properly implicate class certification, and instead, are a ruse to revisit the settled relevant market definition issue and, accordingly, should be denied.

Sincerely,

/s/ Lori A. Fanning
Lori A. Fanning

Cc: Counsel of Record (via email and ECF)